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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/682,483	10/09/2003	George Goicoechea	BSI-210US6	1455
23122	7590	05/21/2007		
RATNERPRESTIA P O BOX 980 VALLEY FORGE, PA 19482-0980			EXAMINER BLANCO, JAVIER G	
			ART UNIT 3738	PAPER NUMBER
			MAIL DATE 05/21/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/682,483

Applicant(s)

GOICOECHEA ET AL.

Examiner

Javier G. Blanco

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 March 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 54-85 is/are pending in the application.
- 4a) Of the above claim(s) 63-65, 72 and 76 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54-62, 66-71, a73-75, and 77-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 October 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/463,987.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>8/16/2004; 8/9/2006; 2/20/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. Applicants' cancellation of claims 1-53 in the reply filed on October 9, 2003 is acknowledged.
2. The document/paper filed October 9, 2003 (10/09/2003) indicates that claims 54-76 are copied from US PG Pub 2002/0147492 (10/032,230), now abandoned.
3. The document/paper filed October 13, 2005 (10/13/2005) indicates that new claims 82 - 85 are copied from US PG Pub 2004/0204753 (10/755,703), currently being prosecuted.

Election/Restrictions

4. Applicants' election with traverse of **Invention/Group I** (claims 54-75 and 77-85), **Stent: Species B** (embodied in Figure 6), **Means for securing juxtaposed apices: Species A** (embodied in Figure 4b), and **Introducer: Species A** (embodied in Figure 8) in the reply filed on March 8, 2007 is acknowledged. The traversal is on the ground(s) that "claims are never species". This is not found persuasive.

As the Examiner indicated in the Restriction Requirement of November 22, 2006, claims 54-76 are copied from US 2002/0147492, and claims 82-85 are copied from US 2004/0204753. The Figures of the instant application are different from the Figures of each of US 2002/0147492 and US 2004/0204753. Since (i) both independent claims 54 and 63 are copied from the same application (i.e., **US 2002/0147492**), (ii) the Figures from said application (i.e., **US 2002/0147492**) clearly show both species, and (iii) the Figures of the instant Application does not have show/present that subject matter, then the Examiner deemed proper to indicate those

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patentably distinct structural and/or functional limitations (i.e., Claim 54: “*wherein the first and second segments and the connector are formed from a single length of wire*”; Claim 63: “*wherein the first tubular segment has a different radial strength than the second tubular segment*”) as separate species.

Further, M.P.E.P. 809.02(a) clearly discloses: “In the absence of distinct figures or examples to identify the several species, the mechanical means, the particular material, or other distinguishing characteristic of the species should be stated for each species identified. If the species cannot be conveniently identified, the claims may be grouped in accordance with the species to which they are restricted”.

The requirement is still deemed proper and is therefore made FINAL.

5. Claim 63-65 and 76 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected Invention and Species, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on March 8, 2007. It should be noted that dependent claim 72 is drawn to one of the non-elected **Means for securing juxtaposed apices** Species C, D, and E (embodied in Figures 4d, 4e, and 4f; see paragraph 0077). Therefore, claim 72 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species.

Priority

6. The instant application is a continuation of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part

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of Application No. 08/312,881 (prosecution suspended). The instant application also claims priority on Foreign Application No EP94401306.9 and Foreign Application No EP94400284.9.

Adequate Written Description

7. According to **M.P.E. P. 2304.092(d)**, “An applicant is not entitled to an interference simply because applicant wants one. The interfering claim must be allowable, particularly with respect to the written description supporting the interfering claim. Historically, an applicant provoked an interference by copying a claim from its opponent. The problem this practice created was that differences in the underlying disclosures might leave the claim allowable to one party, but not to the other; or despite identical claim language differences in the disclosures might require that the claims be construed differently. Rather than copy a claim literally, the better practice is to add (or amend to create) a **fully supported claim** and then explain why, despite any apparent differences, the claims define the same invention. 37 CFR 41.203(a). The problem of inadequate written description in claims added or amended to provoke an interference is so great that the issue has been singled out for heightened scrutiny early in the course of an interference. 37 CFR 41.201, under “Threshold issue.””

Since (i) claims 54-76 are copied from US 2002/0147492, (ii) and claims 82-85 are copied from US 2004/0204753, the Examiner respectfully requests the Applicants to provide support in the original disclosure for each of the limitations claimed in claims 54-76 and 82-85.

Specification

8. The disclosure is objected to because of the following informalities:

a. Please update the CROSS REFERENCE TO RELATED APPLICATION (i.e., “prosecution suspended”). Also, the last two lines of the priority claim are redundant (i.e., both lines claim priority to the same application: 08/312,881). Appropriate correction is required.

Drawings

9. The formal drawings filed October 9, 2003 are objected to because of the following informality: Figure 1a and Figure 1b were not included.

10. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims.

a. Therefore, the “*wherein the first tubular segment has a different radial strength than the second tubular segment*” (see claim 63 at lines 4-5) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

b. Therefore, the “*and at least one of the proximal end and the distal is expandable to a larger diameter than a central section of the prosthesis*” (see claim 69 at lines 3-4) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

c. Therefore, the “*wherein the connection comprises a pivotable connection*” (see claim 71 at line 2) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

d. Therefore, the “*wherein the distal region of the wire support radially expands in response to distally directed anatomical forces on the tubular wire support to increase the resistance to distal migration of the prosthesis*” (see last three lines of claim 82) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

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Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

11. Claims are objected to because of the following informalities:

a. Regarding claim 54, please substitute "tubular segment" (see line 3) with --tubular segments--.

Also, please substitute "second segments" (see line 4) with --second tubular segments--.

Appropriate correction is required.

b. Regarding claim 69, please substitute "end as expandable" (see line 3) with --end as is expandable--. Appropriate correction is required.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 54-62, 66-75, and 77-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over (i) claims 1-18 and 22-24 of U.S. Patent No. 5,716,365; (ii) claims 1-22 of U.S. Patent No. 5,800,508; (iii) claims 1-7 of U.S. Patent No. 6,051,020; (iv) claims 1-82 of U.S. Patent No. 6,117,167; (v) claims 1-16 and 24-29 of U.S. Patent No. 6,165,213; and (vi) claims 11-21 of U.S. Patent No. 6,302,906. Although the conflicting claims are not identical, they are not patentably distinct from each other because the difference between claims 54-62, 66-75, and 77-85 of the application and (i) claims 1-18 and 22-24 of U.S. Patent No. 5,716,365; (ii) claims 1-22 of U.S. Patent No. 5,800,508; (iii) claims 1-7 of U.S. Patent No. 6,051,020; (iv) claims 1-82 of U.S. Patent No. 6,117,167; (v) claims 1-16 and 24-29 of U.S. Patent No. 6,165,213; and (vi) claims 11-21 of U.S. Patent No. 6,302,906 lies in

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the fact that the patent claims include many more elements and is thus much more specific. Thus the invention of (i) claims 1-18 and 22-24 of U.S. Patent No. 5,716,365; (ii) claims 1-22 of U.S. Patent No. 5,800,508; (iii) claims 1-7 of U.S. Patent No. 6,051,020; (iv) claims 1-82 of U.S. Patent No. 6,117,167; (v) claims 1-16 and 24-29 of U.S. Patent No. 6,165,213; and (vi) claims 11-21 of U.S. Patent No. 6,302,906 is in effect a "species" of the "generic" invention of claims 54-62, 66-75, and 77-85. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 54-62, 66-75, and 77-85 of the application are anticipated by (i) claims 1-18 and 22-24 of U.S. Patent No. 5,716,365; (ii) claims 1-22 of U.S. Patent No. 5,800,508; (iii) claims 1-7 of U.S. Patent No. 6,051,020; (iv) claims 1-82 of U.S. Patent No. 6,117,167; (v) claims 1-16 and 24-29 of U.S. Patent No. 6,165,213; and (vi) claims 11-21 of U.S. Patent No. 6,302,906, it is not patentably distinct from (i) claims 1-18 and 22-24 of U.S. Patent No. 5,716,365; (ii) claims 1-22 of U.S. Patent No. 5,800,508; (iii) claims 1-7 of U.S. Patent No. 6,051,020; (iv) claims 1-82 of U.S. Patent No. 6,117,167; (v) claims 1-16 and 24-29 of U.S. Patent No. 6,165,213; and (vi) claims 11-21 of U.S. Patent No. 6,302,906.

Claim Rejections - 35 USC § 112

14. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

15. Claims 63-65, 69, 71-73 and 82-85 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter

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which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

a. Regarding independent claim 63, none of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part of Application No. 08/312,881 (prosecution suspended), Foreign Application No EP94401306.9, or Foreign Application No EP94400284.9 discloses or suggests “*wherein the first tubular segment has a different radial **strength** than the second tubular segment*” (see lines 4-5). Claims 64 and 65 depend on claim 63.

b. Regarding dependent claim 69, none of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part of Application No. 08/312,881 (prosecution suspended), Foreign Application No EP94401306.9, or Foreign Application No EP94400284.9 discloses or suggests “*and at least one of the proximal end and the distal is expandable to a larger diameter than a central section of the prosthesis*” (see lines 3-4).

c. Regarding dependent claim 71, none of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part of Application No. 08/312,881 (prosecution suspended), Foreign Application No EP94401306.9, or Foreign Application No EP94400284.9 discloses or suggests “*wherein the connection comprises a pivotable connection*” (see line 2). Claims 72 and 73 depend on claim 71.

d. Regarding dependent claim 73, none of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part of

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Application No. 08/312,881 (prosecution suspended), Foreign Application No EP94401306.9, or Foreign Application No EP94400284.9 discloses or suggests “*wherein the connection comprises a suture*” (see line 2). Independent claim 54 clearly discloses the “first and second segments and the connector are formed from a single length of wire”.

e. Regarding independent claim 82, none of Application No. 08/463,987 (pending), which is a division of Application No. 08/317,763 (now US 5,609,627), which is a continuation-in-part of Application No. 08/312,881 (prosecution suspended), Foreign Application No EP94401306.9, or Foreign Application No EP94400284.9 discloses or suggests “*wherein the distal region of the wire support radially expands in response to distally directed anatomical forces on the tubular wire support to increase the resistance to distal migration of the prosthesis*” (see last three lines).

Claims 83-85 depend on claim 82.

Because of the procedure outlined in M.P.E.P. 2163.06 for interpreting the claims, it is noted that other art may be applicable under 35 U.S.C. 102 or 35 U.S.C. 103(a) once the aforementioned problem is corrected.

16. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

17. Claims 73, 77, and 79 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. Regarding claim 73, the limitation “*wherein the connection comprises a suture*” (see line 2) is indefinite as to the scope of the invention. Independent claim 54 clearly discloses the “first and

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second segments and the connector are formed from a single length of wire". The suture claimed in claim 73 can't be part of the "single length of wire". Said subject matter will be interpreted as best understood.

b. Regarding claim 77, the limitation "wherein a portion of at least one of said prosthesis segments has a different radiopacity" is indefinite as to the scope of the invention. The claim language does not introduce a point of reference (e.g., a portion, segment, material, or structure) that differs with the radiopacity of said "portion of at least one of said prosthesis segments".

c. Regarding claim 79, the structural relationship between "the wire support comprising at least a first and second axially adjacent tubular segment, joined by a connector extending therebetween; wherein the first and second segments and the connector are formed from a single length of wire" (see independent claim 54 at lines 3-5) and "the first prosthesis segment" and "second prosthesis segment" (see claim 79) is unclear. Does it refer to another "tubular segment" of the "single length of wire"? Does it refer to two separate prostheses connected to the endoluminal prosthesis of claim 54? Critical structure necessary for accomplishing the claimed function must be set forth. Said subject matter will be interpreted as best understood.

Claim Rejections - 35 USC § 102

18. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this

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subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

19. Claims 54-61, 66-71, 77, and 79-83 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by MacGregor (US 4,994,071; cited in Applicants' IDS).

Referring to Figures 1-3, MacGregor discloses an endoluminal prosthesis (10) comprising a tubular wire support (e.g., lattice 16 by itself, or lattices 16 and 22) having a proximal end, a distal end, and a central lumen extending therebetween; the wire support comprising at least a first and a second axially adjacent tubular segments (**first interpretation:** loops 12; **second interpretation:** loops 12 and 12'; **third interpretation:** each of lattice 16 and lattice 22 is a segment; **fourth interpretation:** loop 12 + loop 12' + lattice 22), joined by a connector (connector 14) extending therebetween; wherein the first and second tubular segments and the connector are formed from a single length of wire (i.e., "same wire 24"; see column 4, lines 1-4). Each tubular segment comprises a series of proximal bends and distal bends. Lattice (i.e. prosthesis) 20 is made from single wire 26, it has a "male portion" (e.g., backbone 28) connected to a "female portion" (one end of lattice 16), wherein lattices 16, 22 AND lattice 20 will require at least two introducers for introducing the portions/segments/stents into a branched vessel (see column 5, lines 26-38). The stent could be balloon-expandable (see column 4, line 36 to column 5, line 25) or self-expandable (see column 5, lines 26-38). The endoluminal prosthesis may comprise a polymeric layer (see column 5, lines 45-51). The "outer tubular sleeve surrounding at least a portion of the prosthesis" (see claim 68) could be broadly interpreted as a portion of a catheter or introducer. As disclosed in column 4, lines 30-35, the teachings of MacGregor could be applied to the Palmaz stent (i.e., US 4,733,665).

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Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

20. Claims 54-56, 60, 61, 77, 79, and 80 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Kubo et al. (US 5,236,447 A).

Referring to Figures 1, 2, 3a, 3b, and 5, Kubo et al. discloses an endoluminal prosthesis comprising a tubular wire support (e.g., supporting frame 1) having a proximal end, a distal end, and a central lumen extending therebetween; the wire support comprising at least a first and a second axially adjacent tubular segments (**first interpretation:** rings 2; **second interpretation:** rings 2 and rings 8; **third interpretation:** segments 6 and 6'; **fourth interpretation:** rings 2 + rings 8 + segments 6 and 6'), joined by a connector (Figures 1, 2, 3a, and 3b: connectors 3; Figure 5: connectors 3 and connectors 9) extending therebetween; wherein the first and second tubular segments and the connector are formed from a single length of wire (clearly shown in the Figures; see column 5, lines 35-38). The endoluminal prosthesis may comprise a polymeric layer (e.g., layer 10). As shown in Figure 5, endoluminal prosthesis comprises a main body portion 4, a bifurcated portion 5, and prosthesis/stents 6 and 6', which main body portion 4 and prosthesis/stents 6 and 6' will require at least two introducers for introducing the portions/segments/stents into a branched vessel.

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Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

21. Claims 54-62, 66-71, 77, and 82-85 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cragg (US 5,405,377 A; cited in Applicants' IDS).

Referring to Figures 1-4 and 7-9, Cragg discloses an endoluminal prosthesis (10) comprising a tubular wire support (e.g., supporting frame 11) having a proximal end, a distal end, and a central lumen extending therebetween; the wire support comprising at least a first and a second axially adjacent tubular segments (see tubular segments shown in Figures 1 and 7), joined by a connector (the opposite apices from adjacent hoops meet, therefore are connected) extending therebetween; wherein the first and second tubular segments and the connector are formed from a single length of wire (see column 2, lines 42-49; column 3, lines 33-50). The endoluminal prosthesis may comprise a tubular sleeve made from PTFE (see column 3, lines 15-26). Opposite apices are secured via suture 12 (see column 2, lines 42-49 and lines 60-67). The stent could be balloon-expandable (see column 4, lines 23-30) or self-expandable (see column 2, lines 40-50; column 3, lines 5-12; column 4, lines 4-16).

Note: Claims directed to apparatus must be distinguished from the prior art in terms of structure rather than function. *In re Danly*, 263 F.2d 844, 847, 120 USPQ 528, 531 (CCPA1959).

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“[A]pparatus claims cover what a device is, not what a device does.” *Hewlett-Packard Co. v. Bausch & Lomb Inc.*, 909 F.2d 1464, 1469, 15 USPQ2d 1525, 1528 (Fed. Cir. 1990).

Expressions relating the apparatus to contents thereof during an intended operation are of no significance in determining patentability of the apparatus claim. *Ex parte Thibault*, 164 USPQ 666, 667 (Bd. App. 1969).

Claim Rejections - 35 USC § 103

22. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

23. Claim 78 is rejected under 35 U.S.C. 103(a) as being unpatentable over MacGregor (US 4,994,071; cited in Applicants' IDS) in view of Wolff (US 5,104,404 A; cited in Applicants' IDS).

MacGregor discloses the invention as claimed except for particularly disclosing radiographic indicia defined on at least one segment. However, this is already known in the art. For example, Wolff discloses (see Figures 1-6) an endoluminal prosthesis comprising tubular segments having radiographic indicia (e.g., hinges 14) defined on at least one segment in order to determine the orientation of the endoluminal prosthesis within a vessel (see column 2, lines 22-28; column 3, lines 64-66). Therefore, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to have combined the teaching of an endoluminal prosthesis comprising tubular segments having radiographic indicia defined on at

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least one segment, as taught by Wolff, with the endoluminal prosthesis of MacGregor, in order to determine the orientation of the endoluminal prosthesis within a vessel.

24. Claim 62 and 85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kubo et al. (US 5,236,447 A).

Kubo et al. disclose the invention as claimed except for particularly disclosing PTFE as the sleeve material. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have used PTFE as the sleeve material with the endoluminal prosthesis of Kubo et al., since it has been held to be within the general skill of a worker in the art to select a known material on the basis of its suitability for the intended use as a matter of obvious design choice. *In re Leshin*, 125 USPQ 416.

25. Claim 74 and 75 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cragg (US 5,405,377 A; cited in Applicants' IDS).

Cragg discloses the invention as claimed except for particularly disclosing implanting the endoluminal prosthesis using a catheter no greater than about 16 French. It should be noted that the material of the endoluminal prosthesis of Cragg is capable of being compressed and being inserted into a catheter no greater than about 16 French. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have manufactured the endoluminal prosthesis of Cragg to be implanted using a catheter no greater than about 16 French, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. *In re Aller*, 105 USPQ 233.


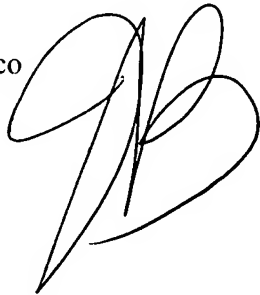
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Javier G. Blanco whose telephone number is 571-272-4747. The examiner can normally be reached on M-F (9:30 a.m.-7:00 p.m.), first Friday of the bi-week off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone numbers for the organization where this application or proceeding is assigned is 571-273-8300 for regular communications and After Final communications. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0858.

Javier G. Blanco

May 8, 2007



David H. Willse
Primary Examiner